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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: **COMBINATORIAL TYPE (SEVERAL VEHICLES WITHIN A HOUSING) CONTROLLED RELEASE DRUG DELIVERY DEVICE**

(57) Abstract: The present invention is a controlled release delivery device. The device comprises more than one vehicle comprising up to 60% by wgt active agent; up to 60% by wgt amino acid; up to 60% by wgt buffer; and up to 70% by wgt polymer. The vehicle(s) are provided within a housing.

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER

 IPC 7 A61K9/22 A61K9/48 A61K31/4422 A61K31/41 A61K31/137
 A61K31/403 A61K31/55 A61P31/18 A61P35/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, MEDLINE, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 940 588 A (GEOGHEGAN EDWARD J ET AL) 10 July 1990 (1990-07-10) column 2, line 60-63 column 4, line 10 -column 8, line 42 column 2, line 65,66 column 3, line 23 -column 4, line 6 column 7, line 32-34 column 7, line 43 column 7, line 58-60	1-24
X	EP 0 960 620 A (RANBAXY LAB LTD) 1 December 1999 (1999-12-01) page 3 '0011! page 2 '0004!	1-24
	-/-	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

30 April 2003

Date of mailing of the international search report

09/05/2003

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

Inventor's name:
 International Application No.
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 840 329 A (BAI JANE PEI-FAN) 24 November 1998 (1998-11-24) claims 1,7 column 7, line 58-65 column 8, line 5-11	1-24
X	WO 90 11070 A (PITMAN MOORE INC) 4 October 1990 (1990-10-04) claims 1,9 page 6, line 31 page 17; example 8	1-24
Y	WO 94 28882 A (CHEN CHIH MING) 22 December 1994 (1994-12-22) page 2/last para - page 3 1st full para	1-24
Y	US 6 228 400 B1 (LEE FANG-YU ET AL) 8 May 2001 (2001-05-08) column 4, line 34 column 4, line 40-42	1-24
Y	US 5 972 389 A (SHELL JOHN W ET AL) 26 October 1999 (1999-10-26) column 5, line 64 -column 6, line 24 column 1, line 67 -column 2, line 2 column 6, line 32 column 6, line 34,35	1-24

INTERNATIONAL SEARCH REPORT

national application No.
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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 1, 3, 4, 8, 11, 13, 16, 17, 18, 19-23, 24 (all in part)
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1, 3, 4, 8, 11, 13, 16, 17, 18, 19-23, 24 (all in part)

Present claims 1, 3, 4, 8, 11, 13, 16, 17, 18, 24 relate to an extremely large number of possible compounds/pharmaceutical formulations. Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the compounds/pharmaceutical formulations claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts relating to the compounds/pharmaceutical formulation:

vehicles (claims 1/24), cf. claim 2
active agents (claims 1/13/16/17/18/24), cf. claims 14 and 15
amino acid (claims 1/13/24) cf. description examples
buffer (claims 1/24), cf. claim 5
polymer (claims 1/24) cf. claim 6
housing (claims 1/24) cf. claim 7

The definition of the vehicle shapes (claim 8) and of the general terms as "cryoprotectant, lyoprotectant and surfactant" (claim 11) are not precise enough and does not render it possible to cover the whole range of the included meaning.

The same holds true for claims 19-23 referring to release order kinetics. It goes without saying that the definition of technical features by parameters does not provide a mean to clearly compare the claimed subject-matter vis-à-vis the prior art, thus rendering it impossible to carry out a complete search which would include any of the existing prior art having the same - implicit - features.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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In ———— national Application No

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